IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ROBERT D. WINDLE III, et al.,	§	
	§	
Plaintiffs,	§	
	§	Civil Action No. 3:11-CV-2591-D
VS.	§	
	§	
SYNTHES USA PRODUCTS, LLC, et al.,	§	
	§	
	§	
Defendants.	§	

MEMORANDUM OPINION
AND ORDER

In this removed action, the court must decide whether the removing defendants have carried their heavy burden of proving the improper joinder of the Texas citizen defendant and whether they have demonstrated the existence of federal question jurisdiction despite plaintiffs' assertion of only state-law claims. Concluding that defendants have done neither, the court grants plaintiffs' motion to remand.

I

Plaintiffs Robert D. Windle III ("Robert") and Gail Windle (collectively, the "Windles") brought this lawsuit in Texas state court against the Synthes defendants,[1] Stephen Wesley Wolfe ("Wolfe"), The University of Texas Southwestern Medical Center at Dallas ("UT Southwestern"); Zale Lipshy University Hospital ("Zale Lipshy"), Kevin Gill M.D.,

[1]The Synthes defendants consist of Synthes USA Products, LLC; Synthes USA Sales, LLC; Synthes (USA) Inc.; Synthes (USA), L.P.; Synthes Spine Company, L.P.; Synthes, Inc.; and Synthes Spine, Inc.

and Kevin Gill M.D., P.A. (collectively, "Dr. Gill"). Their suit arises from Dr. Gill's implantation in Robert of a ProDisc-C Total Disc Replacement device ("ProDisc-C") manufactured and sold by Synthes USA Sales, LLC and Synthes USA Products, LLC (collectively, "Synthes"), and provided to Dr. Gill by Wolfe, a Synthes sales representative.

The Food and Drug Administration ("FDA") approved the ProDisc-C for commercial distribution in 2007. The FDA indicated in its pre-market approval letter ("PMA") that Synthes could begin commercial distribution in accordance with the conditions described in the PMA and the enclosed "Conditions of Approval." The FDA did not approve the ProDisc-C for use in patients who had prior fusion surgery at the same or an adjacent vertebral level or prior fusion surgery at the level to be treated. According to the Windles, Synthes submitted materials to the FDA indicating that the ProDisc-C is expressly contraindicated for such patients. And in the draft ProDisc-C package insert that Synthes sent the FDA, Synthes identified patients with these types of prior fusions in the listed "precautions."

The Windles allege that, once FDA approval was obtained, Synthes did not publish precautionary information regarding prior fusion patients in the sales, marketing, or informational literature that Synthes authored regarding the ProDisc-C. They aver that although Synthes posted a "Patient Information" brochure on its website, the brochure did not mention that the ProDisc-C was not safe or effective for patients with prior fusion surgery at an adjacent vertebral level or at the level to be treated, or that its use in such a

patient was contraindicated and not approved by the FDA.

In 2009 Robert decided to undergo disc replacement surgery using the ProDisc-C. He had previously undergone an anterior cervical discectomy and fusion at the C5-6/C6-7 levels. According to the Windles, Robert based this decision on the advice of his orthopaedic surgeon, Dr. Gill, and on his own research on the ProDisc-C using information provided in the "Patient Information" brochure posted on the Synthes website. Four weeks after his initial meeting with Dr. Gill, Robert underwent cervical spinal surgery at the C4-C5 level using the ProDisc-C. When Robert awakened, he was suffering from paraparesis/paraplegia. Dr. Gill recommended a second surgery to remove and retrieve the ProDisc-C. Robert ultimately underwent three surgeries in April 2009, and he remains a quadriplegic.

According to the Windles' petition, defendant Wolfe, a Synthes sales representative, marketed and sold the ProDisc-C to physicians and hospitals. He was specifically trained in the contraindications for the device. Although not a surgeon, Wolfe was present in the operating suite before and during Robert's initial surgery to provide assistance and support to the surgical team. Wolfe was summoned to the hospital to provide medical assistance, advice, and technical support during Robert's second surgery. The Windles allege that at no time did Wolfe warn Robert of any contraindications applicable to Robert or notify him of any unauthorized or unapproved uses of the device in his case.

The Windles sued the Synthes defendants, Wolfe, UT Southwestern, Zale Lipshy, and

Dr. Gill in Texas state court. They alleged claims for strict liability, negligence products liability, breach of implied warranty of fitness for a particular purpose, conspiracy, and aiding and abetting against all defendants. They asserted claims for breach of express and implied warranties, violations of the Texas Deceptive Trade Practices-Consumer Protection Act ("DTPA"), and fraud against the Synthes defendants and Wolfe. They alleged a claim for common law negligence against Wolfe and respondeat superior/agency against the Synthes defendants. Finally, they alleged claims for assault against Dr. Gill, UT Southwestern, and Zale Lipshy, and a claim under 42 U.S.C. § 1983 against UT Southwestern and Zale Lipshy.

After the Windles' claims against UT Southwestern, Zale Lipshy, and Dr. Gill were dismissed, the Synthes defendants, with the consent of Wolfe, removed the case to this court based on the existence of a federal question and based on diversity of citizenship. They asserted that Wolfe, a Texas citizen, had been improperly joined. The Windles now move to remand, contending that Wolfe has been properly joined and that the court lacks diversity jurisdiction since the parties are not completely diverse citizens.[2] They also argue that there is no federal question jurisdiction because they have not alleged any federal claim against the remaining defendants and their Texas state-law claims do not implicate any federal laws or statutes.

[2]The Synthes defendants are (or were) organized under the laws of the State of Delaware with their principal places of business in the Commonwealth of Pennsylvania.

II

The court considers first whether the Synthes defendants have satisfied their heavy burden of establishing that Wolfe was improperly joined.

A

"The doctrine of improper joinder . . . entitle[s] a defendant to remove to a federal forum unless an in-state defendant has been 'properly joined.'" *Smallwood v. Ill. Cent. R.R. Co.*, 385 F.3d 568, 573 (5th Cir. 2004) (en banc). "When a defendant removes a case to federal court on a claim of improper joinder [of an in-state defendant], the district court's first inquiry is whether the removing party has carried its heavy burden of proving that the joinder was improper." *Id.* at 576. Improper joinder is established by showing that there was either actual fraud in the pleading of jurisdictional facts or that the plaintiff is unable to establish a cause of action against the non-diverse defendant in state court. *Id.* at 573 (citing *Travis v. Irby*, 326 F.3d 644, 646-47 (5th Cir. 2003)).

Under the second alternative—the one at issue in this case—the test for improper joinder "is whether the defendant has demonstrated that there is no possibility of recovery by the plaintiff against an in-state defendant, which stated differently means that there is no reasonable basis for the district court to predict that the plaintiff might be able to recover against an in-state defendant." *Id.* The court must "evaluate all of the factual allegations in the light most favorable to the plaintiff, resolving all contested issues of substantive fact in favor of the plaintiff." *Guillory v. PPG Indus., Inc.*, 434 F.3d 303, 308 (5th Cir. 2005)

(citation and internal quotation marks omitted). Thus "[t]he party seeking removal bears a heavy burden of proving that the joinder of the in-state party was improper." *Smallwood*, 385 F.3d at 574.

There are two "proper means for predicting whether a plaintiff has a reasonable basis of recovery under state law." *Id.* at 573.

> The court may conduct a [Fed. R. Civ. P.] 12(b)(6)-type analysis, looking initially at the allegations of the complaint to determine whether the complaint states a claim under state law against the in-state defendant. Ordinarily, if a plaintiff can survive a Rule 12(b)(6) challenge, there is no improper joinder.

Id. (footnote omitted). In cases where "a plaintiff has stated a claim, but has misstated or omitted discrete facts that would determine the propriety of joinder . . . the district court may, in its discretion, pierce the pleadings and conduct a summary inquiry." *Id.* Although this is a matter for the court's discretion, "a summary inquiry is appropriate only to identify the presence of discrete and undisputed facts that would preclude plaintiff's recovery against the in-state defendant." *Id.* at 573-74. The court is not permitted to "mov[e] . . . beyond jurisdiction and into a resolution of the merits." *Id.* at 574.

B

The Synthes defendants characterize the Windles' claims against Wolfe as "essentially failure to warn claims" based on "the allegation that Mr. Wolfe failed to warn regarding [the] use of ProDisc-C in a patient with a prior fusion surgery at the same or adjacent level." Ds. Resp. 7-8, 9. They argue that because under Texas law a medical

device sales representative does not owe an independent duty to warn, there is no reasonable possibility that the Windles can recover against Wolfe on any of their claims.

The flaw in defendants' argument is that not all of the Windles' claims against Wolfe are failure to warn claims. For example, the Windles allege that Wolfe violated § 17.46(a) and (b) of the DTPA through affirmative actions other than failing to warn. They allege, *inter alia*, that Wolfe "[c]ause[d] confusion or misunderstanding as to the source, sponsorship, approval or certification of goods," "[r]epresent[ed] that goods have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have," and "[a]dvertis[ed] goods with an intent not to sell them as advertised." Pet. ¶ 63. The Synthes defendants do not expressly argue that there is no possibility that the Windles could recover against Wolfe on their DTPA claim. And even if defendants are correct that Texas law precludes the Windles from bringing a failure to warn claim against Wolfe, they have not met their "heavy burden" of establishing that there is no possibility the Windles could prevail against Wolfe on a DTPA claim.

In determining whether Wolfe was improperly joined, the court must "evaluate all of the factual allegations in the light most favorable to the plaintiff, resolving all contested issues of substantive fact in favor of the plaintiff." *Guillory*, 434 F.3d at 308 (citation and internal quotation marks omitted). Moreover, "[b]ecause state court plaintiffs should not be required to anticipate removal to federal court, the court assesses the sufficiency of the factual allegations of [the] complaint under Texas' notice pleading standard." *Warren v.*

State Farm Mut. Auto. Ins. Co., 2008 WL 4133377, at * 4 (N.D. Tex. Aug. 29, 2008) (Fitzwater, C.J.) (collecting cases). Under the Texas Rules of Civil Procedure, a petition shall contain "a short statement of the cause of action sufficient to give fair notice of the claim involved." Tex. R. Civ. P. 47(a). "That an allegation be . . . of legal conclusion shall not be grounds for objection when fair notice to the opponent is given by the allegations as a whole." Tex. R. Civ. P. 45(b). Texas' "fair notice" pleading standard "looks to whether the opposing party can ascertain from the pleading the nature and basic issues of the controversy and what testimony will be relevant at trial." *Penley v. Westbrook*, 146 S.W.3d 220, 232 (Tex. App. 2004), *rev'd on other grounds*, 231 S.W.3d 389 (Tex. 2007); *see also Green Tree Acceptance, Inc. v. Pierce*, 768 S.W.2d 416, 421 (Tex. App. 1989, no writ) (describing "Texas' traditionally liberal pleading principles").

Considering the Windles' allegations as a whole, the court holds that the Synthes defendants have failed to carry their heavy burden of demonstrating that there is no possibility that the Windles can recover against Wolfe on their DTPA claim. The DTPA provides consumers a cause of action for false, misleading, or deceptive acts or practices. *See* Tex. Bus. & Com. Code Ann. § 17.50(a) (West 2011); *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex. 1996). The elements of a DTPA claim are: (1) the plaintiff was a consumer; (2) the defendant either engaged in false, misleading or deceptive acts (i.e., violated a specific laundry-list provision of the DTPA) or engaged in an unconscionable action or course of action; and (3) the DTPA laundry-list violation or unconscionable action

was a producing cause of the plaintiff's injury. *Amstadt*, 919 S.W.2d at 649; *see also Doe v. Boys Clubs of Greater Dall., Inc*., 907 S.W.2d 472, 478 (Tex. 1995). The Windles allege that Wolfe engaged in several of the false, misleading, and deceptive acts declared unlawful under § 17.46(a) and (b) of the DTPA and that Wolfe's actions were unconscionable, as that term is defined in the DTPA. They also assert that Windle relied, to his detriment, on Wolfe's misrepresentations and other deceptive trade practices in deciding to have his surgery.

Where, as here, there is a reasonable possibility that the plaintiffs can recover against the in-state defendant on *any one of their claims*, the case must be remanded. *See, e.g.*, *Shioleno Indus., Inc. v. Liberty Mut. Fire Ins. Co.*, 2012 WL 176572, at *4 (N. D. Tex. Jan. 6, 2012) (Toliver, J.) (citations omitted); *see also B., Inc. v. Miller Brewing Co.*, 663 F.2d 545, 549 n.8 (5th Cir. 1981) ("if there is even a possibility that a state court would find a cause of action stated against any one of the named in-state defendants . . . then the federal court must find that the in-state defendant(s) have been properly joined"). Because the Synthes defendants have failed to meet their heavy burden of demonstrating that there is no possibility that the Windles can recover against Wolfe on their DTPA claim, the court concludes that Wolfe was not improperly joined.

III

The court considers next whether the Synthes defendants have demonstrated that the court has federal question jurisdiction. As the parties invoking federal jurisdiction, the Synthes defendants bear the burden of demonstrating the existence of a federal question. *In re Hot-Hed Inc.*, 477 F.3d 320, 323 (5th Cir. 2007).

A

"Federal courts are courts of limited jurisdiction. [A court] must presume that a suit lies outside this limited jurisdiction, and the burden of establishing federal jurisdiction rests on the party seeking the federal forum." *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001). "[B]ecause the effect of removal is to deprive the state court of an action properly before it, removal raises significant federalism concerns, which mandate strict construction of the removal statute." *Carpenter v. Wichita Falls Indep. Sch. Dist.*, 44 F.3d 362, 365-66 (5th Cir. 1995) (citations omitted). "Doubts regarding whether removal jurisdiction is proper should be resolved against federal jurisdiction." *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 339 (5th Cir. 2000).

Article III, Section 2, Clause 1 of the United States Constitution provides, in relevant part: "The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority[.]" "Although the constitutional meaning of 'arising under' may extend to all cases in which a federal question is 'an ingredient' of the action, [the Supreme Court has] long construed the statutory grant of federal-question jurisdiction as conferring

a more limited power." *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 807 (1986) (citations omitted). "[T]he question whether a claim 'arises under' federal law must be determined by reference to the 'well-pleaded complaint[.]'" *Id.* at 808 (citing *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9-10 (1983)). Aside from complete preemption, which is not applicable here,[3] "[r]emoval is not possible unless the plaintiff[s'] 'well pleaded complaint' raises issues of federal law sufficient to support federal question jurisdiction." *Rodriguez v. Pacificare of Tex., Inc.*, 980 F.2d 1014, 1017 (5th Cir. 1993) (citing *Louisville & Nashville R.R. Co. v. Mottley*, 211 U.S. 149, 152 (1908)).

The "arising-under" provision for federal-question jurisdiction is invoked "by and large by plaintiffs pleading a cause of action created by federal law (*e.g.*, claims under 42 U.S.C. § 1983)." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). But a court can determine that a state-law claim "arises under" federal law if the state-law claim "necessarily raise[s] a stated federal issue, actually disputed and substantial,

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[3] "There is an exception, however, to the well-pleaded complaint rule." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 207 (2004).

> "[W]hen a federal statute wholly displaces the state-law cause of action through complete pre-emption," the state claim can be removed. This is so because "[w]hen the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law."

Id. at 207-08 (alterations in original) (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003)). The Synthes defendants do not rely on complete preemption to support removal. *See* Ds. Resp. Br. 23 ("Synthes' Notice of Removal does not rely on complete preemption to provide federal question jurisdiction.").

which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314. "In other words, federal question jurisdiction exists where (1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008).

B

The Synthes defendants do not dispute that the Windles allege only state-law claims. They make a *Grable*-based argument, however, and contend that they satisfy all four *Singh* elements.[4] They contend that "Plaintiffs' claims are federal as pled on the *face* of Plaintiffs' Petition." Ds. Resp. Br. 23 (emphasis in original). And they posit that the Windles "concede that their claims are federal in nature and require proof that Defendants violated multiple federal requirements" because the Windles state in their remand motion that they are asserting claims for defendants' "failure to follow the FDA's regulations, the requirements set out in the PMA process, and the specifications and procedures in relation to the subject product, the ProDisc-C." *Id.* at 24.

The Synthes defendants posit that the Windles' "[p]etition raises substantial federal issues related to FDA regulation of ProDisc-C, and, in particular, FDA requirements for the ProDisc-C labeling imposed through the PMA process and FDA regulations and guidances

[4]They cite another case rather than *Singh*, but they recite the four elements found in *Singh* and argue that they have satisfied them.

related to medical device labeling intended for lay persons." *Id*. at 23. They assert that

> [a]s stated in Plaintiffs' Petition, the basis for all of Plaintiffs' claims against Defendants is that ProDisc-C was labeled in "direct violation or contravention" to FDA requirements because the Patient Information Brochure did not warn "that the product was not safe or effective for patients with prior fusion surgery at an adjacent vertebral level or the level to be treated."

Id. The Synthes defendants cite as an example the allegation in the Windles' strict liability claim that "because [ProDisc-C] was inappropriately labeled by the Synthes defendants and marketed by all of the Defendants [.] . . [ProDisc-C] was defective and unsafe for its intended use, *in direct violation or contravention of the terms and conditions of the product's approval as outlined or specified in the PMA*." *Id.* (alterations, except correction of ellipsis, and emphasis in original). They also cite the allegation of the petition that the Synthes defendants' "*circumvention of the warning process required by the FDA* . . . caused the Synthes Defendants and Wolfe to market in the United States a device that is inherently dangerous to particular patients without warning those patients of the danger(s)." *Id.* (alterations and emphasis in original).

The Synthes defendants maintain that the Windles' right to relief necessarily depends "on resolution of the issue of whether Defendants circumvented the premarketing approval process set out by the FDA[.]" *Id.* (quoting *Reider-Gordon v. Synthes Spine Co., L.P.*, 2010 U.S. Dist. LEXIS 69343, at *17 (C.D. Cal. June 22, 2010)). They conclude that, "in order to recover under *any* theory, Plaintiffs must prove that Defendants violated federal requirements. As such, an essential element of Plaintiffs' claims, as pled on the face of

Plaintiffs' Petition, is the interpretation of various federal requirements." Ds. Resp. Br. 23-24 (emphasis in original).

C

The court concludes that the Synthes defendants have failed to carry their burden of demonstrating the existence of a federal question. To satisfy the "arising under" requirement based on *Grable*, it is not enough to assert that a state-law claim involves federal law in some respect. *See New Orleans & Gulf Coast Ry. Co. v. Barrois*, 533 F.3d 321, 338 (5th Cir. 2008) (concluding that merely stating that state-law claim raises a "disputed and substantial question of federal law" and that claim implicates "strong federal interest" is insufficient to satisfy *Grable* when defendant did not identify state claim that met the three requirements of *Grable*). Nor is "the mere presence of a federal issue in a state cause of action" sufficient. *Merrell Dow*, 478 U.S. at 813. For example, assume that the FDA required that a patient be furnished certain information before consenting to a particular procedure, and the patient brought suit under state law against the responsible party who failed to furnish the required information. The patient's state-law claim might very well require proof of noncompliance with federal law as an element of the claim, but it would not necessarily require resolving a *substantial federal issue*. The issue could be as straightforward as deciding whether the responsible party did or did not furnish the information required by FDA regulation. Therefore, to rely on *Grable*, the Synthes defendants must first be able to identify the federal issue, then demonstrate that the federal issue is actually disputed, and then show that the

federal issue is substantial.[5] They have not met this burden.

In their response brief, the Synthes defendants appear to use the word "issue" to refer, not to a *substantial issue* as Supreme Court precedent intends, but to describe what is more aptly thought of as federal *subject matter*. But a state-law claim can involve federal *subject matter* without involving a *substantial federal issue*. The closest the Synthes defendants come to specifying a federal *issue* is their quotation from the district court's opinion in *Reider-Gordon*. The quoted passage states that the plaintiffs' right to relief in that case necessarily depended on resolving the issue of whether the defendants had circumvented the premarketing approval process set out by the FDA. The Synthes defendants also maintain—without specifying a particular issue—that each of the Windles' claims requires "the interpretation of various federal requirements." But if the Synthes defendants rely on the issue of circumvention of the FDA premarketing approval process or of interpretation of federal requirements, they should be able to state succinctly what *substantial federal issue* is presented by at least one of the Windles' state-law claims.

This deficiency is illustrated by defendants' reliance on the premise that the Windles' claims are federal in nature because they require proof that defendants violated multiple federal requirements. Is there a substantial federal issue involved, or do the federal requirements on which plaintiffs rely simply function as undisputed standards for

[5]Of course, the fourth requirement, which they make no apparent effort to satisfy, is a showing that federal jurisdiction will not disturb the balance of federal and state judicial responsibilities.

determining under state law whether defendants committed a state-law tort or violated a state consumer protection statute? Defendants also cite the petition's allegation that the Synthes defendants circumvented the warning process required by the FDA, causing the Synthes defendants and Wolfe to market a device that is inherently dangerous to particular patients without warning of the dangers. But what is the issue? If the claim merely requires determining whether defendants did or did not make an FDA-required disclosure, the issue is whether the failure to make the disclosure renders defendants liable under a pleaded theory of state law, which does not necessarily require the resolution of a substantial federal issue.

To take a final example, defendants contend that the basis for all of the Windles' claims is that ProDisc-C was labeled in direct violation or contravention of FDA requirements because the Patient Information Brochure did not warn that the product was not safe or effective for patients with prior fusion surgery at an adjacent vertebral level or the level to be treated. Again, absent a sufficient explanation from defendants, the issue would appear to be whether defendants did or did not include in the brochure a warning that the FDA required. But this is not of itself a substantial federal issue. It is not materially different from, say, a state-law claim based on the failure to comply with a federal regulation that required warning women who are pregnant not to take a particular prescription medication. Such a claim does not necessarily involve a substantial federal issue. Of course, state-law claims that involve federal requirements and standards *can* involve substantial federal issues, but in cases such as *Grable*, the state-law claim expressly stated its dependence on legal standards defined by federal law. *See, e.g., Grable,* 545 U.S. at 314-15

(noting that Grable premised his superior title claim in state court on "a failure by the IRS to give it adequate notice, as defined by federal law," such that "notice within the meaning of the federal statute" was an essential element of the quiet title claim).

The Synthes defendants have failed to identify the substantial federal issue that is actually disputed and that must be resolved before at least one of the Windles' state-law claims can be resolved. In turn, they have therefore failed to show that the court has federal question jurisdiction over at least one of the Windles' state-law claims.

* * *

Accordingly, the court holds that the Synthes defendants have failed to satisfy their heavy burden of establishing that Wolfe—the in-state defendant—was improperly joined and have also failed to demonstrate the existence of a federal question. The court therefore grants plaintiffs' October 31, 2011 motion to remand because the court lacks subject matter jurisdiction. *See* 28 U.S.C. § 1447(c). This action is remanded to County Court at Law No. 2 of Dallas County, Texas. The clerk shall effect the remand in accordance with the usual procedure.

SO ORDERED.

April 13, 2012.

SIDNEY A. FITZWATER
CHIEF JUDGE